K131489

JUN 25 2013

510(k) SUMMARY

Tractus TissueMapper Image Recording System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tractus Corporation

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Date Prepared: March 21, 2013

Name of Device and Name/Address of Sponsor

Tractus TissueMapper Image Recording System

Tractus Corporation

2010 Crow Canyon Place Suite #100

San Ramon, CA 94583

Common or Usual Name: System, Imaging, Pulsed Echo, Ultrasonic

Regulation Number: 21 CFR 892.1560

Product Code: IYO

Device Class: Class II

Predicate Device: Civco Electromagnetic Tracking System (K092619)

Intended Use / Indications for Use:

The Tractus TissueMapper Image Recording System is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

Technological Characteristics

The **TissueMapper** Image Recording System consists of:

- the Tractus TissueMapper Image Recording System Application software
- the Tractus TissueMapper Image Recording System hardware

The ***TissueMapper Image Recording System*** is an electronic image recording and storage system. The device is an accessory to standard ultrasound systems and allows the digital recording images from those standard ultrasound devices, along with the spatial position coordinates of the recorded images.

The images are recorded from the video out port of the standard ultrasound device. The images are recorded as output from the video output of the standard ultrasound imaging device. Brightness, contrast, and gamma are not adjusted by the program. Images are recorded using Video Graphics Array (VGA) or Digital Video Interface (DVI) video output formats. Images are displayed and saved as uncompressed, 8-bit grayscale images. No loss of data occurs with this image format.

The Imaging probe location is monitored and location identifiers are stored with each recorded image. Magnetic location sensors are attached to the hand-held ultrasound imaging probe via a clip. The accuracy of the absolute location of any image recorded with the ***TissueMapper Image Recording System*** is intended to allow identification of a region of interest in a subsequent review and allow accurate placement of an ultrasound probe in another, subsequent, diagnostic ultrasound procedure. As such, the system specifications are that the device will accurately locate that region of interest, thus the absolute location of the probe, within one-half of the width of the ultrasound probe. This accuracy is not sufficient to determine the appropriate placement of a needle (for biopsy) or tissue marker, or to direct other interventional procedures without real-time imaging. Interventional procedures should be guided by standard real-time imaging techniques (such as real-time, hand-held, ultrasound guidance) and should not be performed solely with the TissueMapper images. Image location, relative to previously defined anatomic marker (such as the nipple), is accurate to within ½ of a probe width (3cm in the case of the Ultrasonix L14l-5W/60 60mm linear transducer). Image location, relative to the previously recorded image is accurate to within 1 mm.

The Imaging probe location is monitored and location identifiers are stored with each recorded image. Magnetic location sensors are attached to the hand-held ultrasound imaging probe via a clip. Images are not reviewed on the ***TissueMapper Image Recording System*** for diagnostic or screening findings. Clinical review of recorded images is performed at a separate workstation and that workstation is not a component of the ***Tractus TissueMapper Image Recording System***. Images are reviewed for quality only (shadowing, etc.).

The **TissueMapper Image Recording System** requires the following:

- **Tractus Image Recording System** Application software which will run on a computer with display with the following specifications listed below

- Off-the-Shelf Tower PC Computer to run **TissueMapper Image Recording System** application software, which meets the following requirements
  - Minimum 500 GB Hard Drive
  - Minimum 2.5GHz processor
  - Operating System: Linux
  - Minimum 8GB RAM
  - Minimum Quad-core processor
  - Certified to UL/IEC 60950 ITE standard
  - ≥4 USB Ports of USB 2.0 or better
  - Wired Ethernet
- Computer User Interface
  - Keyboard
  - Display
    - Minimum display size 17"
    - Minimum display resolution 1280x1024
  - Trackball pointing device
- Off-the-Shelf Framegrabber
  - PCI Framegrabber card inserted into tower computer card slot of computer noted above
  - Video cable from ultrasound system to Framegrabber
- Off-the-Shelf probe position detection subsystem (Ascension Technologies)
  - Sensor position interface electronics (Ascension DriveBay) inserted into tower computer card slot of computer noted above
  - Sensor position transmitter (Ascension MRT) and electronics connected to DriveBay by cable
  - Three position sensors (Ascension) and electronics connected to DriveBay by cables
  - Urethane clip for affixing three position sensors to ultrasound transducer
- Off-the-Shelf 3 pedal foot-switch connected to PC by USB interface
- Off-the-Shelf cart with wheels for mounting computer system
- Off-the-Shelf isolation transformer certified to UL2601 connecting computer to power source
- Mounting structure for position transmitter
- Off-the-shelf media storage (USB) to move **Tractus TissueMapper Image Recording System** image files from off-the-shelf computer noted above to another computer (PC) running **Tractus TissueMapper Reviewer** Application

Pursuant to 809.92(a)(6), basically, both the applicant's device ("**Tractus TissueMapper Image Recording System**") and the predicate device ("**Civco Electromagnetic Tracking System**"), allow for spatially mapping with calibrated

spatial positioning devices for subsequent review, employ electromagnetic sensors to detect the location of an ultrasound transducer for a registration of transducer location with respect to the region of body scanned with ultrasound, allow for collection of ultrasound images gathered in the course an ultrasound scan and include software products that run on PC computers. The only technological difference between the **Tractus TissueMapper Image Recording System** and its predicate ("**Civco Electromagnetic Tracking System**") is the **TissueMapper Image Recording System** will always be used in a non-sterile procedure setting, thus it does not require the sterile sensor covers that may be used with the **Civco Electromagnetic Tracking System** if a sterile procedure is performed. Both the applicant's device ("Tractus TissueMapper Image Recording System") and the predicate device ("Civco Electromagnetic Tracking System") are accessories to an Ultrasonic Pulsed Echo Imaging System that have a Moderate Level of Concern.

The Tractus TissueMapper Image Recording System software is Safety Class B according to ANSI/AAMI/IEC 62304:2006. Determination of the LOC and Safety Class is the result of risk assessment activities per ISO 14971.

TRACTUS CORPORATION TISSUEMAPPER IMAGE RECORDING SYSTEM

SUBSTANTIAL EQUIVALENCE CHART

	[Tractus TissueMapper Image Recording System, k TBD]	[Civco Electromagnetic Tracking System, k092619]
Intended Use	***The Tractus TissueMapper Image Recording System*** is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.	The device is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.
Indications for Use	Same as above	Same as above
User Population	Skilled medical professionals	Skilled medical professionals
Technological Characteristics	Accessory to System, Imaging, Pulsed Echo, Ultrasonic; Ultrasonic Pulsed Echo Imaging System	Accessory to System, Imaging, Pulsed Echo, Ultrasonic; Ultrasonic Pulsed Echo Imaging System
Primary component(s)	Software: Position Sensor Monitoring, Image presentation and recording, user interface Hardware: Position Sensor Clip (electromagnetic), Sensor Transmitter, Control Computer	Software: Position Sensor Monitoring, Image presentation, user interface Hardware: Position Sensor Clip (electromagnetic), Sensor Transmitter, Control Computer
Accessories	Media storage (USB)	Sensor covers
Virtual Navigator Software	Yes	Yes
Primary Application	Abdominal, Small Parts (Breast)	Abdominal, small parts
Tracking System	Electromagnetic (Ascension)	Electromagnetic (Ascension)
Registration	External and Internal Marker (one scan plane)	External and Internal Marker (one scan plane)
Safety Features	Risk analysis developed in accordance with ISO 14971	Not available in 510(k)
Software	Yes	Yes
3-D Rendering	Yes	Yes
Supported Imaging Modalities	Ultrasound	Ultrasound
Software level of concern	Moderate level of concern	Moderate level of concern
Standards used and testing performed	EMC testing per IEC 60601-1-2; leakage current testing per IEC 60601-1-1; performance, verification and validation testing performed per internal procedures	Not available in 510(k)

Electrical Testing

EMC testing per IEC 60601-1-2 and leakage current testing per IEC 60601-1-1 were performed for the TissueMapper Image Recording System. All test results were acceptable for the TissueMapper Image Recording System.

Performance Data

Performance, Verification and Validation testing for TissueMapper Image Recording System was performed per internal procedures to ensure that all functional requirements have been met, and that core functions execute as expected. Testing was conducted in-house by trained personnel in a simulated work-environment using phantoms to obtain the functional and accuracy test results. Registration accuracy tests were performed to ensure that the registration and correspondence between ultrasound meets or exceeds specified criteria. The test methodology employed was similar to that of the Civco predicate device, conducted by targeting locations within a phantom and confirming that the selected target location based on the registration calculation is within the same tolerance range or better than the Civco predicate device. System Validation Testing of the Tractus TissueMapper Image Recording System was performed on 2 breast phantoms with 11 masses total randomly positioned. All 11 of the masses were successfully identified.

The results of these tests demonstrate that the TissueMapper Image Recording System validation is within specification.

As such, TissueMapper Image Recording System is as safe and effective as the predicate devices and is substantially equivalent to existing products on the market today. The software performs as well as, or better than legally marketed predicate devices.

Tractus' TissueMapper Image Recording System indications for use are drawn from the indications for use of a legally marketed predicate device: Civco Electromagnetic Tracking System. Tractus TissueMapper Image Recording System draws from features of this predicate device and does not provide novel functionality. As such, the features provided by Tractus TissueMapper Image Recording System do not in themselves raise new concerns of safety or effectiveness.

In all instances, the **TissueMapper Image Recording System** functioned as intended and **the operation** observed was as expected.

Substantial Equivalence

> The **TissueMapper Image Recording System** is as safe and effective as the **Civco Electromagnetic Tracking System**. The **TissueMapper Image Recording System** has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the **TissueMapper Image Recording System** and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the **TissueMapper Image Recording System** is as safe and effective as **Civco Electromagnetic Tracking System Application** Thus, the **TissueMapper Image Recording System** is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

Tractus Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131489
Trade/Device Name: TractusTissueMapper Image Recording System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: May 22, 2013
Received: May 29, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131489

Device Name: Tractus TissueMapper Image Recording System

Indications for Use:

The Tractus TissueMapper Image Recording System is intended to provide physicians with tools for electromagnetic tracking of instruments with respect to image data.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

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